IQVIA LABORATORIES

In Vitro Immunology Services for Lead Selection and Optimization

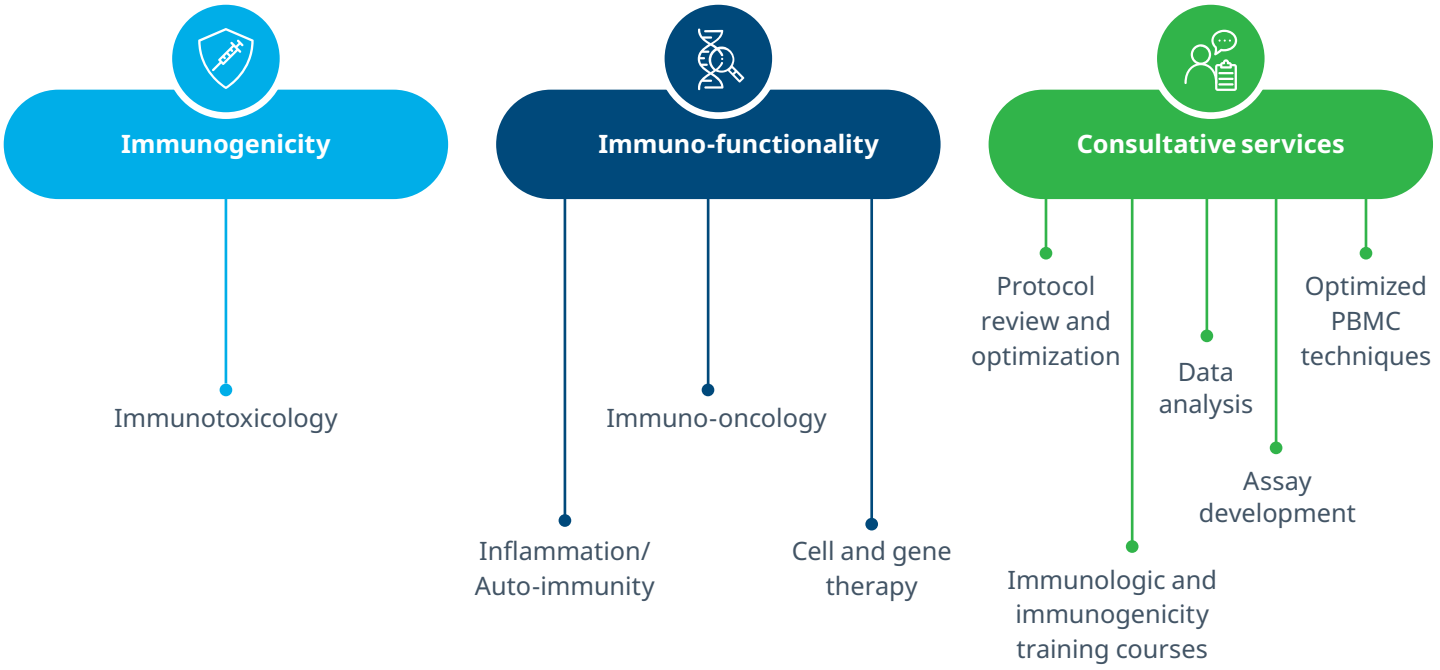
Our in vitro immunology lab provides insights into immune-mediated events via in silico and cell-based in vitro assays. Using primary human samples from our internal biobank, immune cell activation and proliferation can be assessed using flow cytometry or cytokine readouts.

Located in Gosselies, Belgium, our in vitro immunology lab performs unwanted immunogenicity screenings using T-cell activation and proliferation as a surrogate marker for the induction of anti-drug antibodies, cytokine release assays, and MHC-associated peptide proteomics (MAPPS). In addition, immuno-functional screening assays can be performed for drug candidates in immuno-oncology, autoimmune conditions, cell and gene therapy, and other disease areas. Our scientists and biostatistician can also provide hands-on training, protocol review and other consultative services.

Expertise across molecule types

We support clients in advancing programs from discovery to pre-IND and exploratory clinical stages through broad experience in addressing unique challenges across all molecule types. Our team is experienced with an array of new modalities such as novel anti-oncolytic molecules, cell and gene therapy products, monoclonal antibodies (mAb), bispecific antibodies, new antibody formats, antibody-drug conjugates, small molecules, vaccines and generic peptides.

In vitro immunology



Immunogenicity for lead selection

Comprehensive immunogenicity options to improve the safety and efficacy of biotherapeutics and de-risk your pipeline

In silico methods for low-cost, high-throughput assessment

- Computer-based assessment of T-cell epitopes for HLA-binding risk
- Sequence-based assays enable rapid assessment of large numbers of lead candidates
- Useful for evaluating unwanted immunogenicity

In vitro early/innate assays

Our in vitro assays include flow cytometry, cytokine profiles, and ELISpot options

- Cytokine release assay — using whole blood or PBMCs (human and NHP); customizable up to 60 cytokines
- Dendritic cell (DC) activation/maturation assay
- Monocyte activation assayReporter cell line assay

MHC-associated peptide proteomics (MAPPS assay)

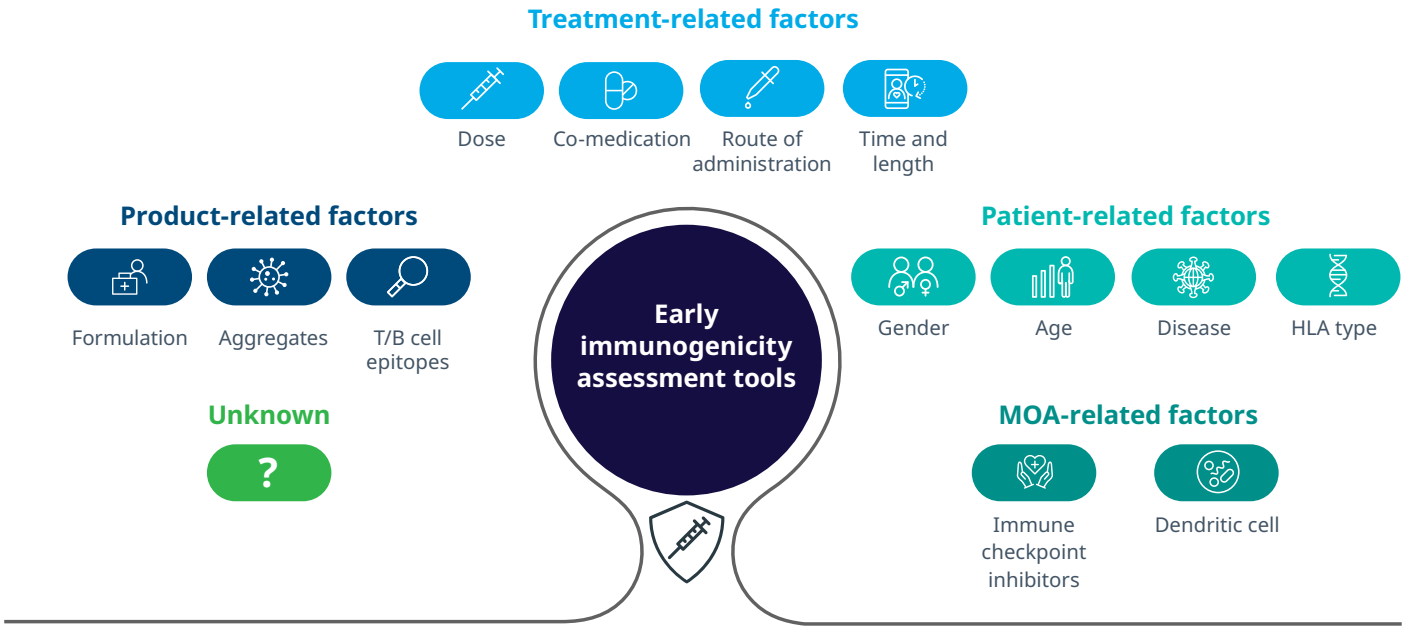
- Specialized mass spec technique to determine which peptides are presented on the cell surface of MHC molecules by professional antigen-presenting cells
- Often followed by a peptide assay to evaluate T-cell responses and identify the immunodominant epitopes

Anti-drug antibody (ADA) assay

- Evaluates pre-existing anti-drug antibodies present in global or specific populations

In vitro T-cell assays

- CD8-depleted PMBC assay — T-cell proliferation by flow cytometry
- DC/T-cell assay — appropriate for immunomodulatory molecules known to directly interact with T-cells; T-cell proliferation by flow cytometry
- Peptide assay — ultrasensitive Fluorospot assay; customizable up to 4 cytokines



Immuno-functionality applications

Proven expertise in assessing lead candidates in immuno-oncology, auto-immunity, infection/inflammation, and cell and gene therapy

Our in vitro immunology team helps evaluate functionality prior to first-in-human administration, advancing approximately 150 programs a year to the next phase. We perform highly customized screening and selection for PD-1/PDL-1 candidates and a wide range of first- and second-generation immune checkpoint inhibitors. Our scientists 'think with you' to understand and support your study-specific needs.

Our immuno-functionality services include:

T-cell assays

- Mixed lymphocyte reaction (MLR) assay
- Antigen-specific (re-)activation assay
- Treg suppression assay
- Exhausted T-cell assays

Myeloid cell assays

- Macrophage polarization and suppression assays
- Macrophage activation assay
- Macrophage inflammatory assay
- Antibody-dependent cellular phagocytosis (ADCP) assays

Killing assays

- PBMC killing assay
- Pan T-cell killing assay
- Neutrophil killing assay
- Complement-dependent cytotoxicity assay
- Antigen-specific killing assay

Natural killer (NK) cell assays

- NK activation assay
- Antibody-dependent cellular cytotoxicity (ADCC) assay
- NK proliferation assay
- Neutrophil assays
- Neutrophil activation assays

DC assays

- DC activation/maturation assay
- DC:T Fluorospot assays (direct ex vivo and enriched)

3D spheroid culture model

- PBMC co-culture binding assays

Cynomolgus assays

- Mixed lmyphocyte reaction (MLR) assay
- Macrophage assays

Consultative services

Our team also supports clients through consultative services and additional training. We provide:

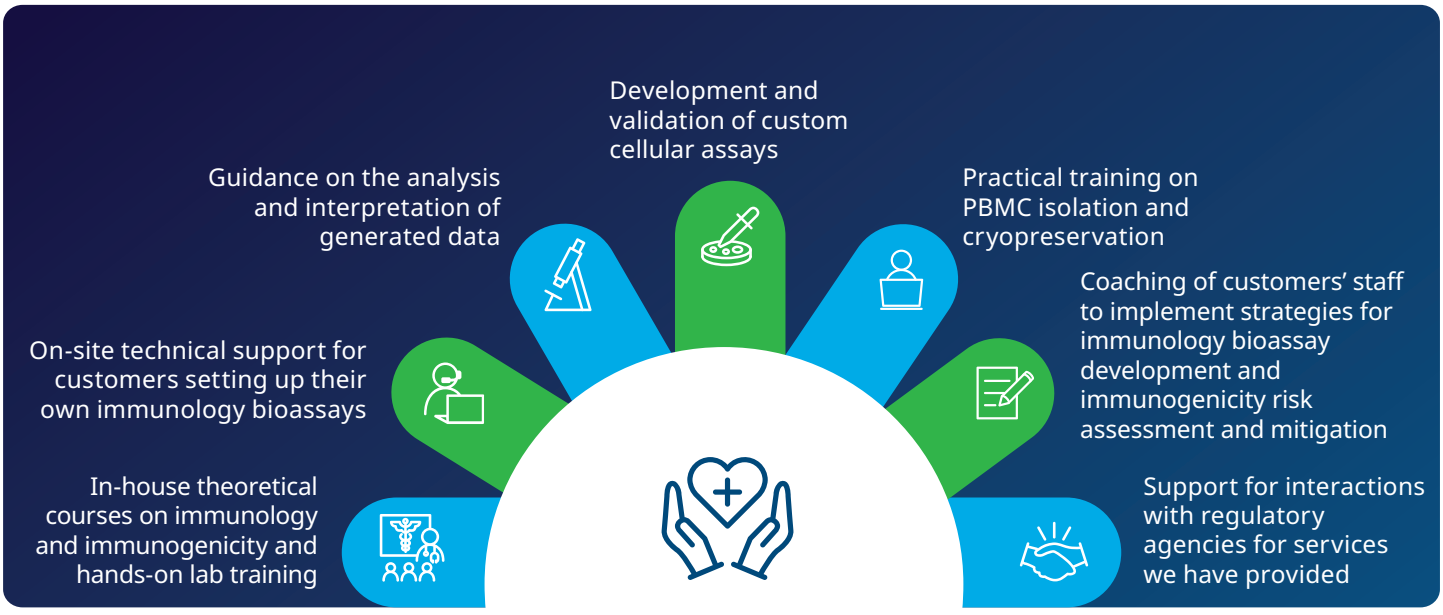
- Theoretical immunogenicity and immunology courses
- Protocol review and optimization
- Data analysis and interpretation
- Hands-on training on the isolation and cryopreservation of PBMCs from whole blood

About us

Our in vitro immunology lab is located in the Brussels South Charleroi Biopark (BSCB) in Gosselies, Belgium. We moved into a new 16,000-square-foot facility in 2024 to better serve our customers' needs.

Our internal biobank

Our laboratory holds a BSL-2+ license as well as a Belgian Biobank License. We store high-quality PBMC samples from more than 1300 healthy donors with 4-digit HLA typing to ensure appropriate representation of diverse global populations. This ensures that our assays use high-quality PBMCs that maintain their functionality. We work with select clinical units and under strict quality controls for optimal specimens.



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